

### REMARKS

The Examiner required restriction, under 35 U.S.C. §§ 121, 372, between Groups 1 to 88 as these inventions or groups of inventions allegedly are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In response, Applicants hereby elect, with traverse, Group 16, claims 3-9 and 11-12, drawn to a polynucleotide of SEQ ID NO:16 encoding the polypeptides of SEQ ID NO:5 vector, host cell and method of making the polypeptide, respectively.

Applicants traverse the restriction requirement on the grounds that the search and examination of at least Groups 16 and 5 (Group 16 is drawn to the polynucleotides of SEQ ID NO:16 and Group 5 is drawn to the polypeptides of SEQ ID NO:5) is not unduly burdensome. According to MPEP section 803 “if a search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent and distinct inventions.” As the polynucleotides of Group 16 encode the polypeptides of Group 5, Applicants suggest examination of at least Groups 16 and 5 can be made without serious burden to the Examiner.

Applicants further traverse the restriction requirement because the unity of invention standard must be applied in national stage applications. Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter “MPEP”) provides that

when the Office considers international applications . . . during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111 . . . .

In applying PCT Rule 13.2 to . . . national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2 . . . .

MPEP at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage (filed under 35 U.S.C. 371) applications.

*Id.* at page 1800-149, col. 1.

Indeed, according to Example 17, Part 2 of Annex B to the PCT Administrative Instructions, the Examiner is obliged to find that "the protein and the DNA sequence exhibit corresponding special technical features" and that, therefore, there is no lack of unity between claims directed to a protein "X" and the DNA sequence that encodes protein "X."

Thus, in the present case, unity of invention does exist at least as between claims 1-2 and 16-17, which cover in part the polypeptides of SEQ ID NO:5 and compositions thereof, and claims 3-9 and 11-12, which cover in part the polynucleotides encoding those polypeptides, including the polynucleotides of SEQ ID NO:16. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-9, 11-12, and 16-17 as drawn to the polypeptides of SEQ ID NO:5 and the polynucleotides of SEQ ID NO:16, and examine those claims in a single application.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 19-0741. If a fee is required for an extension of time under

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37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should be charged to our Deposit Account.

Respectfully submitted,

Date 7/15/04

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